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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,300	07/05/2001	Achim Berthold	R00282US (#90568)	8251

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D. PETER HOCHBERG CO. L.P.A.
1940 EAST 6TH STREET
CLEVELAND, OH 44114

EXAMINER	
GOLLAMUDI, SHARMILA S	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 03/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/830,300	BERTHOLD, ACHIM	
	Examiner	Art Unit	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33-40* is/are pending in the application.

4a) Of the above claim(s) *8-14,23 and 26-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Request for Continued Examination filed on 7/30/04 and Supplementary Response filed 11/24/04 is acknowledged. Claims **33-40** are pending in this application. Claims 8-14, 23, and 26-32 are withdrawn from consideration and claims 1-7, 15-22, and 24-25 stand cancelled.

Request for Information Rule 1.105

Applicant and the assignee of this application are required under 37 CFR 1.105 to provide the following information that the examiner has determined is reasonably necessary to the examination of this application.

The examiner notes that US patent 5,023,084 to Chien et al may anticipate the instant invention since example 8 discloses 1) a first adhesive layer that contains estrogen and a pressure sensitive adhesive, wherein the pressure sensitive polymer has a Tg below room temperature (however the specific Tg is not given of Durotak), 2) a separating layer containing polyisobutylene polymer, and 3) a third adhesive layer that contains progestin and a pressure sensitive adhesive wherein pressure sensitive polymer has a Tg below room temperature (however the specific Tg is not given of Durotak). Thus, the claims would be anticipated since Chien's first layer would correlate to instant Tg1, Chien's separating layer would correlate to instant Tg2, and Chien's third layer which is taught to have the same glass transition temperature as the first layer, would correlate to instant Tg3. However, the glass transition temperature of Oppanol B80 (Tg2) is not provided in the reference and after a search of the respective properties of the respective polymer, the examiner has not been able to ascertain the glass transition temperature of Durotak 80-1054 and BASF Oppanol B80. Therefore, if the applicant has information of the glass transition temperature of the Durotak 80-1054 and Oppanol B80 or is

capable of ascertaining the glass transition temperature, then the information is requested since if the Tg of Oppanol is higher than that of Durotak, it will anticipate the claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 33-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant claims a therapeutic system wherein the system contains at least three polymer layers wherein the first layer has a Tg1, the second layer has a Tg2, and the third layer has a Tg3 that is identical or different to the first layer's glass transition temperature. Upon further consideration and a careful review of the specification, the examiner notes there is only support for at least two *polymer containing* layers as seen on page 8 of the instant specification and there can be up to five layers in total which includes three polymer layers, a backing layer, and protective layer as seen on page 10. Thus, is appears applicant only has support for *at least two* polymer containing layers but not at least three since there is only support for a maximum of three polymer containing layers and not more. Note that "at least two polymer containing layer" provides a scope for three polymer containing layers which is supported by the specification and drawing whereas "at least three polymer containing layer" provides a scope of greater than three

polymer containing layers, which the specification does not have support for. Thus, "at least three polymer containing layers" is new matter.

Furthermore, if the system does in fact contain three polymer layers, the system can only have two layers with different glass transition temperatures and not three. Thus, it appears the recitation "the glass temperature Tg1 of the polymer of the first layer and the glass transition temperature of the Tg3 of the polymer of said third layer are identical *or different* does not have support since there is only support for the first layer and third layer having identical glass temperatures. Therefore, "different" is new matter. The examiner notes that in the office action dated 7/2/03 wherein the examiner suggested that the third layer be defined as Tg3, but this suggestion was based on the assumption there was support for the amended word "different".

If applicant contends there is support, the applicant is requested to point to the exact page and line of the instant specification.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 33-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Otsuka et al (5,151,271) by itself or in view of Patnode et al (6,063,838).

Otsuka et al teaches a pressure sensitive adhering composite medicinal preparation to provide drug supply to the skin. The composite comprises at least two layers, namely at least one pressure-adhering macromolecular layer substance layer and polymer layer adjacent. See abstract. The polymer layer contains a polymer or copolymer that has a glass transition temperature (Tg) of not lower than –50 degrees Celsius, preferably –45 to +45. See column 2, lines 20-25. This allows an increased degree of diffusion therein of the drug and adjuvant but also does not deteriorate the physical strength. See column 2, lines 55-65. The macromolecular layer functions to secure the preparation to the skin, be compatible with the drug and adjuvant, and allow release of the drug. This layer has pressure sensitive polymers with a Tg of –70 to –10 degrees Celsius. This temperature allows increased shape holding property, does not cause skin irritation, and does not leave a residue when peeled off. See column 3, lines 1-25. Further, the macromolecular layer contains the drug and adjuvant. The examples teach the use of two layers with different glass transition temperatures. For instance, example 1 teaches the macromolecular layer containing a drug with a Tg of –55 degrees C and the polymer layer with a Tg of –13 degrees C. The macromolecular layer is coated onto a release liner. The polymer layer is coated onto a polyester film. Note the polyester layer read on the protective layer. Then the polymer film is pressed onto the macromolecular layer. Lastly, Otsuka teaches the use of various percutaneous drugs and the combination of two or more. See column 5, lines 15-51.

Although Otsuka suggest more than two polymer layers, the reference does not exemplify the third layer.

Firstly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to look to the guidance of Otsuka and incorporate a third polymer containing layer (Otsuka' macromolecular or polymer layer). One would have been motivated to do so since Otsuka teaches that the composite should contain *at least* two layers; therefore suggesting the incorporation of more than one polymer layer and/or macromolecular layer respectively. Therefore, if one desired to utilize different drugs or higher concentration of the drug, one would have been motivated to utilize another macromolecular layer, which has a lower glass temperature. Further, the claims recite that the temperature of the third layer may be the same or different than Tg1, thus opening this layer to having any temperature and not denoting any criticality to this layer with regard to temperature. Thus, an additional layer may be applied to the system as suggested by Otsuka and seen in instant invention.

Patnode et al teach a blended pressure-sensitive adhesive which is formed from at least two polymeric materials wherein at least one is a pressure sensitive adhesive. Patnode teaches the transdermal art provides for several types of matrices and all devices basically contain a drug formulation, an adhesive to maintain contact with the patient's skin, a release liner to protect the device in storage, and a backing. See column 12, lines 60-66. Patnode teaches a embodiment wherein a multilaminate device contains a backing, an adhesive layer which contains the drug and excipients, a membrane that controls the rate at which the drug is diffused to the skin, a second adhesive layer, and a release layer. See column 13, lines 20-30 and Figure 15.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Otsuka et al and Patnode and utilize a third polymer layer. Patnode teaches a multilaminate device containing a backing, an adhesive layer which contains the drug and excipients, a membrane that controls the rate at which the drug is diffused to the skin, a second adhesive layer, and a release layer. Therefore one would have been motivated to look to Patnode et al who teach a multilaminate transdermal device to construct Otsuka's suggested device.

Claims 33-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Otsuka et al (5,151,271) by itself or in view of Chien et al (5023084).

Otsuka et al teaches a pressure sensitive adhering composite medicinal preparation to provide drug supply to the skin. The composite comprises at least two layers, namely at least one pressure-adhering macromolecular layer substance layer and polymer layer adjacent. See abstract. The polymer layer contains a polymer or copolymer that has a glass transition temperature (Tg) of not lower than –50 degrees Celsius, preferably –45 to +45. See column 2, lines 20-25. This allows an increased degree of diffusion therein of the drug and adjuvant but also does not deteriorate the physical strength. See column 2, lines 55-65. The macromolecular layer functions to secure the preparation to the skin, be compatible with the drug and adjuvant, and allow release of the drug. This layer has pressure sensitive polymers with a Tg of –70 to –10 degrees Celsius. This temperature allows increased shape holding property, does not cause skin irritation, and does not leave a residue when peeled off. See column 3, lines 1-25. Further, the macromolecular layer contains the drug and adjuvant. The examples teach the use of two layers with different glass transition temperatures. For instance, example 1 teaches the macromolecular

layer containing a drug with a Tg of –55 degrees C and the polymer layer with a Tg of –13 degrees C. The macromolecular layer is coated onto a release liner. The polymer layer is coated onto a polyester film. Note the polyester layer read son the protective layer. Then the polymer film is pressed onto the macromolecular layer. Lastly, Otsuka teaches the use of various percutaneous drugs and the combination of two or more. See column 5, lines 15-51.

Although Otsuka suggest more than two polymer layers, the reference does not exemplify the third layer.

Firstly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to look to the guidance of Otsuka and incorporate a third polymer containing layer (Otsuka' macromolecular or polymer layer). One would have been motivated to do so since Otsuka teaches that the composite should contain *at least* two layers; therefore suggesting the incorporation of more than one polymer layer and/or macromolecular layer respectively. Therefore, if one desired to utilize different drugs or higher concentration of the drug, one would have been motivated to utilize another macromolecular layer, which has a lower glass temperature. Further, the claims recite that the temperature of the third layer may be the same or different than Tg1, thus opening this layer to having any temperature and not denoting any criticality to this layer with regard to temperature. Thus, an additional layer may be applied to the system as suggested by Otsuka and seen in instant invention.

Chien et al disclose a transdermal system that provides a combination of drugs (estrogen and progestin) in a unit dosage. Example 8 teaches the transdermal contains a first adhesive layer that contains the estrogen and a pressure sensitive adhesive, a separating layer containing

polyisobutylene polymer, and a third adhesive layer that contains the progesten and a pressure sensitive adhesive.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to look to the guidance of Otsuka et al and Chien et al and incorporate a third macromolecular drug containing layer. One would have been motivated to do so since Otsuka teaches that the composite should contain *at least* two layers; therefore suggesting the incorporation of more than one polymer layer and/or macromolecular layer respectively. Further, Chien teaches a multilaminate device containing a first adhesive layer with a first drug which correlates to Otsuka's macromolecular layer, a separating layer which correlates to Otsuka's polymer layer, and another adhesive layer containing a second layer, which correlates to Otsuka's second macromolecular layer. Therefore, if one desired to utilize different drugs for combination therapy as known in the prior art, one would have been motivated to utilize another macromolecular layer, which has a lower glass temperature than the polymer layer.

Response to Arguments

Although the rejections have been modified, the examiner has retained the primary reference, Otsuka et al, and thus addresses the arguments pertaining to this reference.

Applicant argues that Otsuka teaches does not unambiguously teach that the two polymer layers should have different glass temperatures (Tg) since the glass temperatures have overlapping ranges. Thus, applicant argues that the two layers in Otsuka can have the same Tg whereas instant invention requires different Tg temperatures. Therefore, it is argued that a motivation to modify the system as seen in instant invention is not present. Secondly, applicant

argues that Otsuka has a different goal of preventing drug crystallization whereas instant invention addresses the problem of cold-flow phenomenon, i.e. the cohesion of the system.

Applicant's arguments have been fully considered but they are not persuasive. Applicant claims a therapeutic system, a method of treating using the system, and a process of making the system. The system contains three layer Tg1, Tg2, and Tg3. Tg1 and Tg2 have different temperatures wherein Tg2 has a higher glass transition temperature. Tg1 and Tg3 may have the same or different temperature.

The prior art, Otsuka teaches *at least* two layers, at least one macromolecular layer and at least one polymer layer. Note column 2, lines 1-15. The first polymer layer has a Tg of not lower than –50 Celsius and preferably –40 to +75 or –40 to +45 Celsius. The second layer has a Tg of –70 to –10 Celsius and preferably –55 to –10 Celsius. It is implicit that these layers have different temperatures since the polymer layer's temperature range is higher than the macromolecular temperature range. Although, it is noted that there is a small overlapping range, the examples effectively demonstrates Otsuka's implicit teaching of two different temperatures. All the examples provide for the polymer layer having a higher temperature than the macromolecular layer. Therefore, applicant's limitation that one layer has a higher temperature than the other is met. Secondly, Otsuka teaches the utilization of more than two layers. The claims recite that the temperature of the third layer may be the same or different than Tg1, thus opening this layer to having any temperature and not denoting any criticality to this layer in regards to temperature. Thus, an additional layer may be applied to the system as suggested by Otsuka and applicant's third layer requirement is met under obviousness. Also, Otsuka teaches that the preparation provides a greater amount of drug since the respective layers contain the drug compared to one

layer containing the drug, which further provides motivation to utilize more than two layers if one desired a system that contained a high amount of drug. Thus, it is the examiner's position that the prior art reads on the instant claims since the criticality of the invention lies in the two layers having different Tg temperatures with a third layer having any temperature and the prior art teaches two layers with different temperatures and the suggestion of more than two layers.

With regard to the applicant's goal and prior art's goal, the examiner points out that the use of a patent, as a reference is not limited to what inventive goal or problem is, it is literature of art for all it contains. Therefore, even though applicant's invention is directed is "cold-flow" and Otsuka has a different "goal", Otsuka teaches applicant's a similar system, the use of the system, and method of making the system.

Accordingly, the rejection is maintained.

Conclusion

None of the claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharmila S. Gollamudi
Examiner
Art Unit 1616

SSG

GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600